

1. (Currently amended) A pharmaceutical composition which ~~comprises~~ consists essentially of orlistat and a pharmaceutically acceptable bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex, and optionally comprises excipients.
2. (Currently amended) The composition according to claim 1, wherein the composition ~~comprises~~ consists essentially of (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant, and optionally comprises excipients.
3. (Currently amended) The composition according to claim 2, which ~~comprises~~ consists essentially of:
  - (a) from about 5 to about 1000 mg of orlistat;
  - (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of DEAE-cellulose, guanidinoethylcellulose, and DEAE-Sephadex;
  - (c) from about 0.1 to about 10 g of a filler;
  - (d) from about 0.05 to about 3.0 g of a surfactant;
  - (e) from about 0.05 to about 2.0 g of a disintegrant;
  - (f) from about 0.02 to about 2.0 g of a binder;
  - (g) from about 0.001 to about 1.0 g of a lubricant;
  - (h) from about 0.1 to about 5.0 g of a flowability enhancer;
  - (i) from about 0.01 to about 4.0 g of a sweetener; and
  - (j) and about 0.001 to about 0.5 g of a colorant.
4. (Currently amended) The compositions according to claim 3, wherein the orlistat is present in an amount of from about 10 to about 500 mg.
5. (Original) The composition according to claim 4, wherein the orlistat is present in an amount of about 120 mg.

6. (Original) The composition according to claim 4, wherein the orlistat is present in an amount of from about 20 to about 100 mg.
7. (Original) The composition according to claim 6, wherein the orlistat is present in an amount of about 60 mg.
8. (Original) The composition according to claim 4, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g.
9. (Original) The composition according to claim 8, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g.
10. (Currently amended) A pharmaceutical composition which ~~comprises~~ consists essentially of orlistat and a pharmaceutically acceptable acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose,  $\beta$ -cyclodextrin, and  $\gamma$ -cyclodextrin, and optionally comprises excipients.
11. (Original) The composition according to claim 10, wherein pharmaceutically acceptable bile acid sequestrant is selected from the group consisting of  $\beta$ -cyclodextrin and  $\gamma$ -cyclodextrin.
12. (Original) The composition according to claim 10, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, sevelamer, DEAE-cellulose,  $\beta$ -cyclodextrin, and  $\gamma$ -cyclodextrin.
13. (Original) The composition according to claim 12, wherein the bile acid sequestrant is selected from the group consisting of cholestyramine, colestipol, and sevelamer.

14. (Original) The composition according to claim 13, wherein the bile acid sequestrant is cholestyramine.

15. (Original) The composition according to claim 13, wherein the bile acid sequestrant is colestipol.

16. (Original) The composition according to claim 13, wherein the bile acid sequestrant is sevelamer.

17. (Currently amended) The composition according to claim 10, wherein the composition ~~comprises~~ consists essentially of (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant, and optionally comprises excipients.

18. (Currently amended) The composition according to claim 17, which ~~comprises~~ consists essentially of:

- (a) from about 5 to about 1000 mg of orlistat;
- (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose,  $\beta$ -cyclodextrin, and  $\gamma$ -cyclodextrin;
- (c) from about 0.1 to about 10 g of a filler;
- (d) from about 0.05 to about 3.0 g of a surfactant;
- (e) from about 0.05 to about 2.0 g of a disintegrant;
- (f) from about 0.02 to about 2.0 g of a binder;
- (g) from about 0.001 to about 1.0 g of a lubricant;
- (h) from about 0.1 to about 5.0 g of a flowability enhancer;
- (i) from about 0.01 to about 4.0 g of a sweetener; and
- (j) and about 0.001 to about 0.5 g of a colorant.

19. (Currently amended) The composition according to claim 14, wherein the composition ~~comprises~~ consists essentially of (a) from about 5 to about 1000 mg of orlistat and (b) from about 0.1 to about 20 g of the bile acid sequestrant, and optionally comprises excipients.

20. (Currently amended) The composition according to claim 19, which ~~comprises~~ consists essentially of:

- (a) from about 5 to about 1000 mg of orlistat;
- (b) from about 0.1 to about 20 g bile acid sequestrant selected from the group consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose,  $\beta$ -cyclodextrin, and  $\gamma$ -cyclodextrin;
- (c) from about 0.1 to about 10 g of a filler;
- (d) from about 0.05 to about 3.0 g of a surfactant;
- (e) from about 0.05 to about 2.0 g of a disintegrant;
- (f) from about 0.02 to about 2.0 g of a binder;
- (g) from about 0.001 to about 1.0 g of a lubricant;
- (h) from about 0.1 to about 5.0 g of a flowability enhancer;
- (i) from about 0.01 to about 4.0 g of a sweetener; and
- (j) and about 0.001 to about 0.5 g of a colorant.

21. (Currently amended) The compositions according to claim 17, wherein the orlistat is present in an amount of from about 10 to about 500 mg.

22. (Original) The composition according to claim 21, wherein the orlistat is present in an amount of about 120 mg.

23. (Original) The composition according to claim 17, wherein the orlistat is present in an amount of from about 20 to about 100 mg.

24. (Original) The composition according to claim 23, wherein the orlistat is present in an amount of about 60 mg.
25. (Original) The composition according to claim 17, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g.
26. (Original) The composition according to claim 25, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g.
27. (Currently amended) The compositions according to claim 19, wherein the orlistat is present in an amount of from about 10 to about 500 mg.
28. (Original) The composition according to claim 27, wherein the orlistat is present in an amount of about 120 mg.
29. (Original) The composition according to claim 27, wherein the orlistat is present in an amount of from about 20 to about 100 mg.
30. (Original) The composition according to claim 29, wherein the orlistat is present in an amount of about 60 mg.
31. (Original) The composition according to claim 19, wherein the bile acid sequestrant is present in an amount of from about 0.5 to about 10 g.
32. (Original) The composition according to claim 31, wherein the bile acid sequestrant is present in an amount of from about 1 to about 5 g.
33. (Currently amended) A kit for use in the treatment of obesity, which comprises (a) a first component ~~which is~~ consisting essentially of orlistat and (b) a second component ~~which is~~ consisting essentially of a bile acid sequestrant selected from the group

Serial No. 10/718,049

Filed: November 20, 2003

consisting of cholestyramine, colestipol, colestimide, colesevelam, sevelamer, DEAE-cellulose,  $\beta$ -cyclodextrin,  $\gamma$ -cyclodextrin, guanidinoethylcellulose, and DEAE-Sephadex, present in oral unit dosage form.

34-37. (Cancelled)